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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,814	03/04/2004	Guy Gorochov	2121-0180P	3637

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EXAMINER

WESSENDORF, TERESA D

ART UNIT PAPER NUMBER

1639

DATE MAILED: 10/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/791,814

Applicant(s)

GOROCHOV ET AL.

Examiner

T. D. Wessendorf

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-12, 15, 16 and 18-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13, 14 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicants' election of Group III, Claims 13-19 in the reply filed on 8/2/2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-12, 15-16 and 18-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/2/2005.

Applicants' election with traverse of SEQ ID NO: 11, (MSPLSSQASA) is likewise acknowledged. [The examiner apologizes for the typographical error "MIP-IG" made in the last Office action. The restriction is made for either RANTES or MIP. Nevertheless, the restriction/election requirement with regards to this species i.e., subgroups 2 and 3 is withdrawn since the single elected species covers this requirement.]

Status of the claims

Claims 1-22 are pending in the application.

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Claims 1-12, 15-16 and 18-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species.

Claims 13, 14 and 17 are under examination.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement (e.g., see specification, pages 27-30). 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

The information disclosure statement filed 3/4/2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

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Specification

The disclosure is objected to because of the following informalities:

1. It contains an embedded hyperlink and/or other form of browser-executable code at e.g., page 2, lines 20-21. Applicants are required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.
2. There is no Seq. ID. No. given for the sequence at page 7, lines 22-23 and page 8, lines 5-14.
3. The reference to a database for the compound RANTES (10-68) at page 27, line 28 is improper, as the recited database is a hyperlink.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors (typographical, grammatical and idiomatic). Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13, 14 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point

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out and distinctly claim the subject matter which applicant regards as the invention.

1. Claim 13 is unclear as to the claimed "obtainable by a method according to anyone of claims 1 to 12 of the following formula."

It is not clear whether a compound is being obtained from the formula of Seq. ID. No. 24 or are the entire generic sequence obtained by anyone of the processes according to claims 1-12.

The use of parenthesis in formula Seq. ID. No. 24-RANTES(10-68) is improper as every feature or compound recited in a claim becomes a part of the overall subject matter. By placing terms in parenthesis renders the claim ambiguous as to whether or not said numbers should be disregarded. Furthermore, reference to the database(NCBI, page 7, line 28) for this sequence is improper. It is suggested that applicants recite for said sequence since this appears to be a part of the claim. [Should applicants include the RANTES (10-68) sequence in the specification, the sequence listing has to correspondingly be changed.]

2. The structure of formula Seq. ID. No. 24 is not in proper format as required by 37 CFR 1.821 through 1.825. It is suggested that the symbols #, & and * be replaced with AA1, AA2 and so forth. See claims 13 and 17.

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3. In claim 14, some of the sequences have been duplicated. For example Seq. ID. 6. Also, some of the species are not encompassed by the generic claim formula, Seq. ID. 24.

4. The use of parenthesis in formula Seq. ID. No. 24-RANTES(10-68) is improper as every feature or compound recited in a claim becomes a part of the overall subject matter. By placing terms in parenthesis renders the claim ambiguous as to whether or not said numbers should be disregarded. Furthermore, reference to the database (NCBI, page 7, line 28) for this sequence is improper. It is suggested that applicants recite for said sequence since this appears to be a part of the claim. [(Claim 17)].

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13, 14 and 17 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hartley et al (Jrnl. of Human, Virology, 2000). Hartley discloses at page 242 a mutant form of RANTES from a library from the N-terminus of RANTES known to be involved in the activation of receptors by bound chemokines. The mutant sequences were extended, mimicking the N-terminal extension. The claimed amino acid structure or sequence is a property inherent to the mutant library of Hartley. The claimed peptide sequence appears to be the same or similar to the prior art, absent a showing of unobvious differences. The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that there is a difference between the RANTES mutant (i.e., library) that the claims are directed to new materials and that such a difference would have been

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considered unexpected by one of ordinary skill in the art, that is, the claimed subject matter, if new, is unobvious. In the absence of evidence to the contrary, the burden is upon the applicants to prove that the claimed library of RANTES is structurally different from those taught by the prior art and to establish patentable differences.

Where the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See *In re Ludtke*, supra. Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same as is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. See *In re Brown*, 59 CCPA 1036, and 459 F.2d 531, 173 USPQ 685 (1972); *In re Best* 195 USPQ 430 (CCPA 1977).

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

T.D. 7
T.D. WESSENDORF
PRIMARY EXAMINER
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10/1/05